Remarks

Claims 1-31 are pending and claims 20-30 have been withdrawn. Claims 12, 13 and 15 have been amended. New claim 31 has been added. Support for the amendments to the claims and the new claim can be found in general throughout Applicants' Specification, and in particular, for example, as follows: claim 12, page 8, lines 8-14, and claim 31, originally filed claim 1 and page 8, lines 8-19. The amendments to the claims correct inadvertent clerical errors and are not related to patentability. Applicants reserve the right to prosecute the claims in their original form in a continuing application. No new matter has been added.

As a preliminary matter, Applicants note that Items BC and BI from Applicants' January 16, 2004 Form 1449 have been crossed out and indicated as having no publication date. Applicants are not aware of the exact publication date of the documents but are resubmitting them under separate cover on a new Form 1449 with dates indicating that they were published prior to the filing date of the above-captioned application. Applicants respectfully request that the Examiner review the same and indicate her review by initialing the Form 1449 and returning a copy of the same to Applicants at the address of record.

Applicants submit that the amendment to claims 12, 13 and 15 render moot the rejection of claims 12, 13, 15 and 17-19 under 35 U.S.C. § 112, second paragraph, and respectfully request that it be withdrawn.

With respect to claims 17 and 18, it is well established that "in reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope...." M.P.E.P. 2173.02. In addition, definiteness of a claim must be analyzed in light of "[t]he claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made." *Id.* The skilled artisan would readily understand that the term "measurably decrease" as used in claims 17 and 18, refers to a decrease in the amount of bacteria present in the urine of an individual that can be measured, e.g., using analytical means. Methods of measuring bacteria in urine are well known. Since the skilled artisan would understand the scope of the term "measurably decrease," claims 17 and 18 are definite. Accordingly, Applicants

submit that the rejection of claims 17-19 under 35 U.S.C. § 112, second paragraph, has been overcome and Applicants respectfully request that it be withdrawn.

Claims 1, 3-10, 13 and 15-18 stand rejected under 35 U.S.C. § 103 over U.S. Patent 6,299,925 (Xiong et al.)

Xiong et al. disclose a water soluble formulation in a granular or tablet form that includes from about 10 % by weight to about 50 % by weight green tea extract. The formulation can optionally include extracts from other plants such as herbal plants, fruits and vegetables. Xiong et al. also disclose that the formulations can include sodium bicarbonate and citric acid.

Claim 1 is directed to a tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent comprising an acid and a base, binder, and lubricant, where the tablet disintegrates in water having a temperature of about 22° C in less than 2.5 minutes. In order to establish a *prima facie* case of obviousness, "the prior art reference (or references when combined) must teach or suggest all of the claim limitations." M.P.E.P. 2142. It is undisputed that Xiong et al. fail to teach or suggest an effervescent tablet that includes at least 200 mg cranberry extract (see, December 1, 2006 Office action, page 4). It is also undisputed that Xiong et al. fail to teach or suggest an effervescent tablet that can disintegrate in water having a temperature of about 22° C in less than 2.5 minutes. *Id.* Xiong et al. thus fail to teach required elements of claim 1. As such a *prima facie* case of obviousness of claim 1 over Xiong et al. has not been made and the rejection of claim 1 under 35 U.S.C. 103 over Xiong et al. cannot stand.

The December 1st Office action takes the position, "The amount of a specific ingredient in a composition and the physical characteristics of the tablet are clearly result effective parameters that a person of ordinary skill in the art would routinely optimize." *Id.* However, it is well established by legal precedent that "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." M.P.E.P. 2144.05. In addition, the case law that has developed around result-effective variables pertains to situations in which a composition is otherwise disclosed in a reference but the particular

claimed range of a component or property of the composition is not expressly taught by the reference. Xiong et al. do not teach an effervescent tablet having a composition within which the composition of the tablet of claim 1 falls. In particular, Xing et al. do not teach an actual composition that includes cranberry extract or that disintegrates in water in any particular period of time. Xiong et al. also do not teach or suggest that the amount of cranberry extract in an effervescent composition is a result effective variable. Rather, Xiong et al. disclose that their composition can include extracts of fruit among a list of other classes of extracts including plants and vegetables. In a separate area of the patent Xiong et al. list a number of fruits from which extracts can be obtained including, e.g., apple, apricot, banana, blue berry, cranberry, cherry, fig, grape, grapefruit, kiwi, lemon, lime, peach, pear, pineapple, orange, papaya, strawberry, tangerine and watermelon (see, Xiong et al., Example 7). Nothing in the two passages from Xiong et al. highlights cranberry extracts or specifies a particular amount of cranberry extract. Xiong et al. also do not teach or suggest that the disintegration time of a tablet in water is a result effective variable. As such, the determination of the amount of cranberry extract in a tablet or the disintegration properties of the tablet cannot be deemed to be a matter of routine experimentation. Accordingly, the result-effective variable theory is inapplicable to the patentability of claim 1. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Xiong et al. is unwarranted and respectfully request that it be withdrawn.

Claims 2-10, 13 and 15-18 are distinguishable under 35 U.S.C. § 103 over Xiong et al. for at least the same reasons as set forth above with respect to claim 1.

Claims 16-18 are further distinguishable under 35 U.S.C. § 103 over Xiong et al. for at least the following additional reasons. Claim 16 is directed to a tablet that includes an effervescent composition that includes from 50 mg to 200 mg cranberry seed oil, and an effervescent agent that includes an acid and a base, the tablet having a hardness of at least 5 kilopounds and disintegrating in water in less than 2.5 minutes. Nowhere in Xiong et al. is there a teaching or a suggestion of cranberry seed oil –let alone including from 50 mg to 200 mg cranberry seed oil in an effervescent composition. Rather, Xiong et al. only disclose that the formulations can include fruit extract (see, Xiong et al., col. 3, lines 7-10, and Example 7). At no point do Xiong et al. teach or suggest that the fruit

extract can be cranberry seed oil. As such, Xiong et al. fail to teach or suggest all of the features of claim 16. Accordingly, a *prima facie* case of the obviousness of claim 16 has not been made and the rejection of claim 16 under 35 U.S.C. § 103 over Xiong et al. cannot stand. Should this rejection be maintained, Applicants respectfully request that the next action identify, by reference to column and line number, the location in Xiong et al. of a teaching of cranberry seed oil.

Claim 17 is directed to a tablet that includes an effervescent composition that includes cranberry extract in an amount sufficient to measurably decrease the amount of bacteria present in the urine of an individual having a urinary tract infection. The tablet further includes an effervescent agent, binder, and lubricant. It is undisputed that Xiong et al. do not teach or suggest a tablet that includes cranberry extract in an amount sufficient to measurably decrease the amount of bacteria present in the urine of an individual having a urinary tract infection (see, December 1st Office action, page 5). Rather, the December 1st Office action takes the position that "since the composition taught by the reference is the same as the claimed composition, the reference composition would intrinsically have to have the same effects if applicant's invention functions as claimed." *Id.* To the extent that the rejection of claim 17 under 35 U.S.C. § 103 over Xiong et al. relies on a theory of inherency, Applicants submit that inherency is not a proper theory on which to base a rejection under 35 U.S.C. § 103. Something that did not exist cannot have any inherent properties. It is undisputed that Xiong et al. did not actually prepare a tablet that included cranberry extract. Therefore Xiong et al. do not teach a tablet that includes cranberry extract. This fact is undisputed. Since Xiong et al. do not teach an actual tablet that includes cranberry extract, it is necessarily the case that no such tablet existed. If the tablet did not exist, it is axiomatic that it could not have had any inherent properties. Accordingly, Xiong et al. cannot be deemed to inherently teach the tablet of claim 17. Applicants submit, therefore, that the rejection of claim 17 under 35 U.S.C. § 103 over Xiong et al. is unwarranted and respectfully request that it be withdrawn.

Claim 18 is further distinguishable under 35 U.S.C. § 103 over Xiong et al. for at least the same reasons as set forth above in distinguishing claim 17.

Claims 11, 12, 14 and 19 stand rejected under 35 U.S.C. § 103 over Xiong et al. in view of U.S. 2003/0161875 (Murpani et al.).

The discussion of Xiong et al. set forth above is incorporate herein by reference.

Murpani et al. disclose tablets that disintegrate and dissolve in the oral cavity without the need of water. The tablets of Murpani et al. include a therapeutically effective amount of drugs that act as COX-2 inhibitors. Murpani et al. also disclose a long list of almost thirty optional fillers that can be added to the composition including aluminum magnesium hydroxide and sorbitol. The optional fillers are selected to give bulk to the COX-2 composition and are physically and chemically compatible with a COX-2 inhibitor.

Claims 11, 12 and 14 depend from claim 1, and claim 19 depends from claim 17. The rejection of claims 11, 12, 14 and 19 is based on the premise that Xiong et al. teach or suggest the composition of claims 1 and 17. Since this premise has been refuted above, the rejection of claims 11, 12, 14 and 19 under 35 U.S.C. § 103 over Xiong et al. in view of Murpani et al. is also unwarranted and cannot stand.

Claims 11, 12, 14 and 19 are further distinguishable under 35 U.S.C. § 103 over the proposed combination of Xiong et al. in view of Murpani et al. for at least the following additional reasons. Claim 11 is directed to the tablet of claim 1 and further specifies that the effervescent agent include sodium bicarbonate and citric acid, and also specifies that the tablet include polyethylene glycol, sorbitol and sodium benzoate. It is undisputed that Xiong et al. fail to teach or suggest an effervescent tablet that includes sorbitol.

Murpani et al. do not cure the deficiencies of Xiong et al. In order to establish a *prima facie* case of obviousness, there must be some suggestion or motivation to modify the reference or combine reference teachings. M.P.E.P. 2142. Here there is no such teaching, suggestion or motivation. Xiong et al. is directed to an effervescent formulation that includes green tea extracts. Murpani et al. is directed to fast dissolving tablets that include a therapeutically effective amount of drugs that act as COX-2 inhibitors. The tablets of Murpani et al. do not include an effervescent agent that includes an acid and a base, and Murpani et al disclose that their tablets "dissolve in the oral cavity in less than about 30 seconds without the need of water." See, Murpani et al., para. [0007].

(Emphasis added). Murpani et al. do not teach or suggest that their tablets are effervescent tablets. As such, the skilled artisan familiar with Xiong et al. would have no reason to look to the disclosure of Murpani et al, since the disclosure of Murpani et al. is not directed to effervescent formulations in general or effervescent formulations that include green tea extract, in particular.

Murpani et al. is further deficient for at least the following additional reasons. Murpani et al. disclose a long list of almost thirty optional fillers that can be added to their composition; sorbitol is included in this list. The optional fillers are selected to give bulk to the COX-2 composition and are physically and chemically compatible with a COX-2 inhibitor. Murpani et al. do not teach or suggest anything about including any of their fillers in effervescent compositions –let alone specifically selecting sorbitol for inclusion in an effervescent composition. Accordingly, the skilled artisan would have no reason to *sua sponte* select sorbitol from among the long list of fillers set forth in Murpani et al. and then include the same in the effervescent composition of Xiong et al. Therefore, and for at least these additional reasons, the rejection of claim 11 under 35 U.S.C. § 103 over Xiong et al. in view of Murpani et al. is unwarranted and Applicants respectfully request that it be withdrawn.

Claim 12 is further distinguishable under 35 U.S.C. § 103 over Xiong et al. in view of Murpani et al. for at least the same additional reasons as set forth above with respect to claim 11.

Claim 14 is directed to the tablet of claim 1 and further specifies that the tablet includes magnesium hydroxide. It is undisputed that Xiong et al. do not teach or suggest a tablet that includes cranberry extract and magnesium hydroxide.

Murpani et al. does not cure the deficiencies of Xiong et al. The tablets of Murpani et al. do not include an effervescent agent that includes an acid and a base. Murpani et al. disclose that their tablets "dissolve in the oral cavity in less than about 30 seconds without the need of water." See, Murpani et al., para. [0007]. (Emphasis added.) Murpani et al. do not teach or suggest that their tablets are effervescent tablets. Murpani et al. also do not describe effervescent formulations in general or effervescent formulations that include green tea extract, in particular. As such, the skilled artisan familiar with Xiong et al. would have no reason to look to the disclosure of Murpani et al.

Murpani et al. is further deficient for at least the following additional reasons. Murpani et al. disclose a long list of almost thirty optional fillers that can be added to their composition; aluminum magnesium hydroxide is included in this list. (Applicants note that Murpani et al. do not expressly teach magnesium hydroxide.) The optional fillers are selected to give bulk to the COX-2 composition and are physically and chemically compatible with a COX-2 inhibitor. Murpani et al. do not teach or suggest anything about including any of their fillers in an effervescent composition –let alone specifically including magnesium hydroxide in an effervescent composition. Accordingly, the skilled artisan would have no reason to *sua sponte* decide to include magnesium hydroxide in an effervescent composition. For at least these additional reasons, the rejection of claim 14 under 35 U.S.C. § 103 over Xiong et al. in view of Murpani et al. is unwarranted and Applicants respectfully request that it be withdrawn.

Claim 19 is further distinguishable under 35 U.S.C. § 103 over Xiong et al. in view of Murpani et al. for at least the same additional reasons as set forth above with respect to claim 14.

Claims 1-10, 13, and 15-18 stand rejected under 35 U.S.C. § 103 over U.S. Patent 6,299,925 (Mann) in view of Xiong et al.

Mann discloses a method of producing a reconstituted fruit, herb and/or seed fiber product and forming tablets that include the reconstituted material. Mann also discloses a tablet that includes cranberry pomace.

The discussion of Xiong et al. set forth above is incorporated herein by reference.

Claim 1 is directed to a tablet that includes an effervescent composition that includes at least 200 mg cranberry extract, an effervescent agent comprising an acid and a base, binder, and lubricant, where the tablet disintegrates in water having a temperature of about 22° C in less than 2.5 minutes. To establish obviousness based upon a proposed combination of references there must be some teaching, suggestion or motivation in the prior art for making the proposed combination. *See Fromson v. Anitec Printing Plates, Inc.*, 132 F.3d 1437 (Fed. Cir. 1997); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, (Fed. Cir. 1998). "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. 2143.01. (Emphasis in original). In addition,

references that teach away cannot serve to create a *prima facie* case of obviousness. *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1131, 1132 (Fed. Cir. 1994). Here there is no teaching, suggestion or motivation to combine the references as proposed in the December 1st Office action. It is undisputed that Mann does not teach or suggest an effervescent tablet --let alone an effervescent tablet that includes 200 mg cranberry extract and that disintegrates in water having a temperature of about 22°C in less than 2.5 minutes (see, December 1st Office action, page 6). Rather, Mann discloses a dried dietary supplement formulation derived from whole cranberries. Mann further discloses that his composition can be "formed into tablets or capsules, in the absence of any colorants, sweeteners, unnatural binders, excipients, or any other accessory ingredients." *Id.* at col. 4, lines 32-35. Mann also discloses that, "[i]n its preferred form, the process does not require any unnatural substances; hence the finished product does not contain any unnatural substances." *Id.* at col. 5, lines 27-30. Mann refers to the dried cranberry formulation as CRANMAX and further discloses that it "can be taken in pill or capsule form to afford an individual the known benefits of cranberry without ingesting unwanted additives such as sweeteners and colorants found in commercially available cranberry concoctions" (*Id.*, col. 6, lines 35-39). Nowhere in Mann is there a teaching or a suggestion of a need to formulate his CRANMAX into a beverage or into a liquid form. Therefore, the skilled artisan would not think to formulate the CRANMAX into an effervescent composition.

Mann also discloses that the bioactive ingredients of his CRANMAX are shielded from degradation during transit through the stomach as a result of being infused into a generally fiber matrix. Mann does not teach or suggest that this shielding will be maintained if the CRANMAX is placed in water prior to ingesting.

Xiong et al. do not cure the deficiencies of Mann. As established above, Xiong et al. do not teach or suggest an effervescent tablet that can disintegrate in water having a temperature of about 22° C in less than 2.5 minutes. As such, the proposed combination of Mann and Xiong et al. fails to teach or suggest all of the elements of the tablet of claim 1. Xiong et al. is further deficient in that Xiong et al. do not teach or suggest how to make an effervescent tablet that can disintegrate in water having a temperature of about 22° C in less than 2.5 minutes. Xiong et al. further fail to teach or suggest how to make

an effervescent tablet that includes at least 200 mg cranberry extract and that can disintegrate in water having a temperature of about 22° C in less than 2.5 minutes. Accordingly, the proposed combination of Mann and Xiong et al. provides the skilled artisan with no clue as to how to achieve the tablet of claim 1.

Xiong et al. is further deficient in that nothing in Xiong et al. teaches or suggests combining their effervescent composition with at least 200 mg cranberry extract. The focus of Xiong et al. is on green tea extract. The focus of Xiong et al. is not on cranberry extract. In addition, Xiong et al. do not teach or suggest that a cranberry extract formulation infused into a fiber matrix, such as the one disclosed in Mann, can be successfully formulated as an effervescent composition while maintaining Mann's desired properties, which include shielding the bioactive ingredients from degradation during transit through the stomach. To the contrary, Xiong et al. disclose that effervescence is thought to be useful in speeding the body's absorption of components associated therewith. Xiong et al. disclose that their formulation is used by dispensing in water and waiting until it is substantially disbursed or dissolved (Xiong et al., col. 3, lines 36-37). According to Xiong et al.:

> "By allowing the formulation to become substantially disbursed or dissolved, the beneficial extract components are unlocked and become more available to the body upon consumption. Additionally the effervescent action of the formulation further agitates and unlocks the beneficial extracts contained therein." (Xiong et al., col. 3, lines 36-43).

Xiong et al. go on to state:

> Such effervescent action creates additional turbulence in the liquid composition, further unlocking the desired extracts by separating them in solution. Therefore, the extracts are more exposed to the digestive forces inside the body, and absorbed at a much greater rate.

*Id.*, col. 4, lines 28-32.

Thus, the skilled artisan would not think to use formulate the CRANMAX of Mann into an effervescent composition because the skilled artisan would have no reason to believe that in doing so he or she would still be able to maintain Mann's goal of shielding the bioactive ingredients in his CRANMAX from degradation during transit

through the stomach. Applicants submit, therefore, that the rejection of claim 1 under 35 U.S.C. § 103 over Mann in view of Xiong et al. has been overcome and respectfully request that it be withdrawn.

Claims 2-10, 13 and 15-18 are distinguishable under 35 U.S.C. § 103 over Mann in view of Xiong et al. for at least the same reasons as set forth above in distinguishing claim 1.

Claims 11, 12 and 19 stand rejected under 35 U.S.C. § 103 over Mann in view of Xiong et al., and in further view of Murpani et al.

The discussion of Mann set forth above is incorporated herein.

The discussion of Xiong et al. set forth above is incorporated herein.

The discussion of Murpani et al. set forth above is incorporated herein.

Claims 11 and 12 depend from claim 1, and claim 19 depends from claim 17. The rejection of claims 11, 12 and 19 is based on the premise that the proposed combination of Mann and Xiong et al. teach or suggest composition of claims 1 and 17. Since this premise has been refuted above, the rejection of claims 11, 12 and 19 under 35 U.S.C. § 103 over Mann in view of Xiong et al., and in further view of Murpani et al. is also unwarranted and cannot stand. Accordingly, Applicants respectfully request that the rejection of claims 11, 12 and 19 under 35 U.S.C. § 103 over Mann in view of Xiong et al., and in further view of Murpani et al. be withdrawn.

Applicant does not comment further on specific features of the dependent claims, but does not acquiesce to the assertions contained in the December 1st Office action, since these issues are presently moot in light of the above analysis.

The claims now pending in the application are in condition for allowance and such action is respectfully requested. The Examiner is invited to telephone the undersigned should a teleconference interview facilitate prosecution of this application.

Please charge any additional fees that may be required or credit any overpayment made to Deposit Account No. 501,171.

Respectfully submitted,

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